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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,696	03/09/2000	James Keith	22058-521	2455

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EXAMINER
SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
1647	14

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/521,696	KEITH ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application (PTO-152)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/01 has been entered. An action on the RCE follows.

2. Claims 1-20 are pending.

3. The text of those sections of title 35, U. S. Code not included in this action can be found in the previous office action (Paper No: 9).

4. Newly submitted claims 12-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claims are drawn to a method of prevention and treatment of complement-mediated cytotoxicity due to necrotic injury which was not previously claimed. Previous claims were drawn to a method of prevention and treatment of complement-mediated cytotoxicity due to tissue transplantation. Although it is possible to pretreat a subject prior to transplantation, it is not possible to anticipate necrotic injury and thus often the treatment is after the injury. Thus, the two methods of inventions are different from each other as they are directed to nonequivalent types of methods.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-20 are withdrawn from consideration

as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

35 USC § 112, second paragraph rejections withdrawn

5. Applicant's arguments have obviated the rejection under 35 USC 112, second paragraph, for being indefinite and failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in claim 4.

35 USC § 102, rejections maintained

6. The rejection of claim 1 35 U.S.C. § 102(a) as anticipated by Hill et al. (1998) is maintained.

Applicant has amended the claim and argues that Hill et al. is generally silent about the relationship between complement-mediated cytotoxicity and administration of IL-11. However, on page 8 of the specification, it is indicated that "immune-mediated disorder" means any disorder characterized by CTL and/or complement-mediated disorder. Furthermore, the specification indicates that IL-11 is administered to prevent immune-mediated disorder. Thus, preventing complement-mediated cytotoxicity is inherent to IL-11. Pretreating a mouse (mammal) with IL-11 prior to transplant will prevent complement-mediated cytotoxicity in said mammal. Therefore, the disclosure of Hill et al. anticipates instant claim 1. Claims 10 and 12 are rejected insofar as they depend on rejected claim 1.

7. The rejection of claim 6 35 U.S.C. § 102(b) as anticipated by Yang et al. (U.S. Patent No. 5,700,664) is maintained.

Applicant has amended the claim and argues that Yang et al. is generally silent about the relationship between complement-mediated cytotoxicity and administration of IL-11. Further they allege that the reference does not teach or suggest that IL-11 can be administered to treat this cytotoxicity. However on page 8 of the specification, it is indicated that "immune-mediated disorder" means any disorder characterized by CTL and/or complement-mediated disorder. Furthermore, the specification indicates that IL-11 is administered to treat immune-mediated disorder. Thus, treating complement-mediated cytotoxicity is inherent to IL-11. Treating of several immune-mediated disorders in patients (mammals) is discussed including dosage regiment (column: 12). Therefore, the disclosure of Yang et al. anticipates instant claim 6. Claim 11 is rejected insofar as it depends on rejected claim 6.

Claim Rejections - 35 USC § 103, rejection maintained

8. Claims 1-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hill et al. (1998) in view of Yang et al. (U.S. Patent No. 5,700,664) is maintained.

Applicant has amended the claims and argues that both Hill et al. and Yang et al. in combination fails to render obvious the invention now claimed. However, Hill and Yang references as discussed above, teach preventing and/or treating complement- mediated cytotoxicity. Further, limitations to these claims have been discussed in Paper No. 9 paragraph 8a. Thus, claims 1-9 are rejected under 35 U.S.C. 103 (a) as being obvious

over Hill et al. (1998), in view of Yang et al. (U.S. Patent No. 5,700,664) is maintained.

New Ground of Rejections

9. The following is a new ground of rejection necessitated by applicants' amendment of claims 1, 3 and 6.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for IL-11 to reduce of the complement- mediated cytotoxicity does not reasonably provide enablement for prevention of complement-mediated cytotoxicity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level

of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification as filed is insufficient to enable one skilled in the art to practice the claimed invention without an undue amount of experimentation. The pretreatment of mammals with IL-11 prior to tissue transplantation will reduce complement-mediated cytotoxicity but does not reasonably provide enablement for the prevention of complement-mediated cytotoxicity. Applicants have demonstrated that by using IL-11 they are able reduce complement-mediated cytotoxicity *in vitro*. However, it is unclear how this will result in the prevention complement-mediated cytotoxicity. Since applicant has not provided any working examples of the efficacy of using IL-11 to prevent complement-mediated cytotoxicity in already established disease subjects or applicable model, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

Given the breadth of claims 1 and 2 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention in prophylactic or therapeutic action on liver disease and following liver transplantation to prevent graft rejection. Claim 10 is rejected insofar as it depends on rejected claim 2.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3 and 6 are rejected as vague and indefinite in the recitation of the phrase "identifying a mammal at risk of developing complement-mediated cytotoxicity or identifying a mammal with complement-mediated cytotoxicity". It is unclear how the mammal at risk is identified. Therefore, the metes and bounds of the claim are unclear. Claim 2, 4, 5 and 7-11 are rejected insofar as they depend on rejected claims 1, 3 and 6.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Hill et al. (1998), in view of Yang et al. (U.S. Patent No. 5,700,664) for reasons discussed above in Paragraph 7.

13. No claims are allowed.

14. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JEFFREY STUCKER
PRIMARY EXAMINER